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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HENKEL, DANIELLE B

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,427	Applicant(s) JACKSON ET AL.	
	Examiner DANIELLE HENKEL	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 15, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29,31,34,35,39,41,42,45,52-55,58-60,63-65 and 93-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 6-29,31,34,35,39,41,42,45,52-55,58-60,63-65 and 93-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed January 15, 2009 has been entered and fully considered.
2. Claims 26-29, 31, 34-35, 39, 41-42, 45, 52-55, 58-60, 63-65, and 93-112 are pending, of which 93-112 are new.

Election/Restrictions

3. Applicant's election of claims 26-29, 31, 34-35, 39, 41-42, 45, 52-55, 58-60, and 63-65 in the reply filed on September 8, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 26-29, 31, 34, 52-53, 58-60, 63-65, 93-98, 103-104, and 107-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACKSON (US 5213619) in view of KOWANKO (US 6036918).

a. With respect to claims 26, 28 and 29, JACKSON teaches a method of cleaning and sterilizing a substrate by contacting it with a carbon dioxide dense fluid mixed with hydrogen peroxide under radiation (components of percarbonic acid) (Column 5, lines 19-22 and Column 9, lines 31-62). The fluid contacts the substrate under high energy (conditions) conducive to decomposing (removing) contaminants and killing organisms (sterilizing) (Column 10, lines 7-18). JACKSON does not explicitly disclose the method in which the fluid is substantially non-aqueous. However, KOWANKO teaches a method of sterilization in which a substantially non-aqueous fluid (vapor, essentially free from any liquid) comprising a peracid (percarbonic is a specific form of a peracid)

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contacts a substrate under conditions conducive to removing contaminants (Column 2, lines 38-47). At the time of the invention it would have been obvious to modify the method of JACKSON to include the percarbonic acid to be provided in a substantially non-aqueous fluid form as taught by KOWANKO because it allows for use of temperatures less than the heat sensitive temperature of the substrate, doesn't require washing steps of using a liquid sterilant, and reduces metal corrosion caused by water (Column 2, lines 45-47, Column 1, lines 37-40, Column 7, lines 39-52).

b. With respect to claims 27 and 31, JACKSON teaches the substrate material to be cleaned and sterilized contains biological contaminants (Column 4, lines 4-7) and that the fluid mixture is useful for cleaning organic, inorganic and ionic residues (Column 10, lines 7-10).

c. With respect to claim 34, JACKSON teaches the dense fluid comprises supercritical or liquefied gases with carbon dioxide being a preferred gas (Column 4, lines 9-34).

d. With respect to claim 35, JACKSON teaches contacting the substrate with an ionized argon gas (plasma) once it has been contacted with the dense fluid (Column 10, lines 19-27).

e. With respect to claims 52 and 53, JACKSON teaches the dense fluid may be a mixture (additive) of argon (noble gas) and carbon dioxide to enhance cleaning ability (Column 5, lines 48-55).

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- f. With respect to claim 58, JACKSON teaches that following the dense fluid operation (after contacting with fluid) residual moisture is ionized to become vapor and subsequently removed (drying) (Column 10, lines 33-37).
- g. With respect to claims 59 and 60, JACKSON teaches the substrate comprises polymeric materials with no biologic reactivity (biocompatible) so they are capable of performing in contact with living tissue and body fluids (Column 2, lines 20-27).
- h. With respect to claim 63 and 64, JACKSON teaches the substrate is a polymeric medical device (Column 2, lines 28-30).
- i. With respect to claim 65, JACKSON teaches the substrate is polymeric medical device including flexible tubing for use inside or outside of the body (endoscope) (Column 2, lines 30-32).
- j. With respect to claim 93, the combination of JACKSON and KOWANKO in claims 26, 28, and 29 above teaches the formation of a substantially non-aqueous percarbonic acid fluid by contacting hydrogen peroxide and carbon dioxide under conditions conducive to formation of percarbonic acid. KOWANKO further teaches vaporizing a liquid solution mixture of a peracid (percarbonic acid) to separate the peracid rich phase from the aqueous phase (water) to form a substantially non-aqueous fluid (vapor) (Column 2, lines 38-65).
- k. With respect to claim 94, KOWANKO also teaches after the acid rich phase is separated from the aqueous phase (vaporized) the acid rich phase is

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further dried (vapor path to remove liquid droplets in vapor) to form the substantially non-aqueous (vapor) fluid (Column 2, lines 56-62).

l. With respect to claim 95, JACKSON teaches a method of cleaning and sterilizing a substrate by contacting it with a carbon dioxide dense fluid mixed with hydrogen peroxide under radiation (components of percarbonic acid) (Column 5, lines 19-22 and Column 9, lines 31-62). The fluid contacts the substrate under high energy (conditions) conducive to decomposing (removing) contaminants and killing organisms (sterilizing) (Column 10, lines 7-18).

JACKSON does not explicitly disclose the method in which the fluid is formed in an external vessel. However KOWANKO teaches a method of sterilizing substrates with a fluid comprising peracid formed in an external vessel (vaporization chamber) and thereafter contacting the substrate with the fluid under conditions conducive to sterilizing (Column 7, line 57 - Column 8, line 25). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the method of JACKSON to include the percarbonic acid being formed in the external vessel as taught by KOWANKO because it allows for the use of a different set of conditions specific to forming the acid and substrate sterilization and allows for connection to multiple sterilization chambers with different sets of conditions for use in bulk sterilization (Column 7, lines 1-27).

m. With respect to claim 96, JACKSON teaches the substrate material to be cleaned and sterilized contains biological contaminants (Column 4, lines 4-7) and

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that the fluid mixture is useful for cleaning organic, inorganic and ionic residues (Column 10, lines 7-10).

n. With respect to claim 97, JACKSON teaches the dense fluid comprises supercritical or liquefied gases with carbon dioxide being a preferred gas (Column 4, lines 9-34).

o. With respect to claim 98, JACKSON teaches contacting the substrate with an ionized argon gas (plasma) once it has been contacted with the dense fluid (Column 10, lines 19-27).

p. With respect to claims 103 and 104, JACKSON teaches the dense fluid may be a mixture (additive) of argon (noble gas) and carbon dioxide to enhance cleaning ability (Column 5, lines 48-55).

q. With respect to claim 107, JACKSON teaches that following the dense fluid operation (after contacting with fluid) residual moisture is ionized to become vapor and subsequently removed (drying) (Column 10, lines 33-37).

r. With respect to claims 108 and 109, JACKSON teaches the substrate comprises polymeric materials with no biologic reactivity (biocompatible) so they are capable of performing in contact with living tissue and body fluids (Column 2, lines 20-27).

s. With respect to claims 110 and 111, JACKSON teaches the substrate is a polymeric medical device (Column 2, lines 28-30)

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t. With respect to claim 112, JACKSON teaches the substrate is polymeric medical device including flexible tubing for use inside or outside of the body (endoscope) (Column 2, lines 30-32).

8. Claims 39 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACKSON (US 5213619) in view of KOWANKO (US 6036918) as applied to claims 29, 31, 34, 52-53, 58-60, 63-65, 93-98, 103-104, and 107-112 above, and further in view of CAPUTO (US 5244629).

a. With respect to claim 39, JACKSON teaches using a plasma gas but does not explicitly disclose using a UV irradiated and weakly ionized plasma. However, CAPUTO teaches a method of sterilizing a substrate with plasma that contains ultraviolet emissions (UV irradiation) and without a large component of ions (weakly ionized) (Column 7, lines 28-41). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the substrate sterilization system of JACKSON to include the plasma being UV irradiated and weakly ionized as taught by CAPUTO because it allows for effective sterilization without corrosion of the substrate due to high concentrations of ions (Column 7, lines 47-49).

b. With respect to claim 99, JACKSON teaches using a plasma gas but does not explicitly disclose using a UV irradiated and weakly ionized plasma. However, CAPUTO teaches a method of sterilizing a substrate with plasma that contains ultraviolet emissions (UV irradiation) and without a large component of ions

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(weakly ionized) (Column 7, lines 28-41). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the substrate sterilization system of JACKSON to include the plasma being UV irradiated and weakly ionized as taught by CAPUTO because it allows for effective sterilization without corrosion of the substrate due to high concentrations of ions (Column 7, lines 47-49).

9. Claims 41-42, 45, 54-55, 100-102, and 105-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACKSON (US 5213619) in view of KOWANKO (US 6036918) as applied to claims 29, 31, 34, 52-53, 58-60, 63-65, 93-98, 103-104, and 107-112 above, and further in view of CHAO (US 5996155).

a. With respect to claim 41, JACKSON does not explicitly disclose the fluid and substrate being irradiated with UV light during contact. However, CHAO teaches a method of sterilizing a substrate in a chamber in contact with liquid carbon dioxide and hydrogen peroxide while being exposed (irradiated) to an ultraviolet radiation source (Column 8, line 58- Column 9, line 4). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the sterilization system of JACKSON to include the irradiation with UV light as taught by CHAO because UV light has proven benefits in disinfecting solid surfaces by controlling pathogens without the use of harmful chemicals (Column 3, lines 23-27).

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b. With respect to claim 42, JACKSON does not disclose UV radiation of a specific wavelength. However, CHAO teaches using UV radiation that is preferably within the range of about 180 to 300 nm (at least 40% wavelength less than 300 nm) (Column 5, lines 44-45) because it disrupts the DNA strands of micro-organisms and prevents cell replication causing death, and microbes are vulnerable to the effects of light in this range because it breaks organic molecular bonds causing cellular and genetic damage to microorganisms (column 3, lines 25-36).

c. With respect to claim 45, JACKSON does not disclose intermittent or continuous UV irradiation. However, CHAO teaches UV radiation may be produced from lamps in continuous or high energy bursts depending upon which is suitable for cleaving specific contaminant bonds (Column 5, lines 54-56).

d. With respect to claims 54 and 55, JACKSON does not disclose translating the substrate during contact with the fluid. However, CHAO teaches translating the fluid in respect to a stationary substrate because the movement is necessary for cleaning specifically transport and distribution of chemical oxidants needed for sterilization and disinfection to contact all portions of the substrate (Column 8, lines 39-57). At the time of the invention it would have been obvious to one of ordinary skill in the art to translate the substrate instead of the fluid, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

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e. With respect to claim 100, JACKSON does not explicitly disclose the fluid and substrate being irradiated with UV light during contact. However, CHAO teaches a method of sterilizing a substrate in a chamber in contact with liquid carbon dioxide and hydrogen peroxide while being exposed (irradiated) to an ultraviolet radiation source (Column 8, line 58- Column 9, line 4). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the sterilization system of JACKSON to include the irradiation with UV light as taught by CHAO because UV light has proven benefits in disinfecting solid surfaces by controlling pathogens without the use of harmful chemicals (Column 3, lines 23-27).

f. With respect to claim 101, JACKSON does not disclose UV radiation of a specific wavelength. However, CHAO teaches using UV radiation that is preferably within the range of about 180 to 300 nm (at least 40% wavelength less than 300 nm) (Column 5, lines 44-45) because it disrupts the DNA strands of micro-organisms and prevents cell replication causing death, and microbes are vulnerable to the effects of light in this range because it breaks organic molecular bonds causing cellular and genetic damage to microorganisms (column 3, lines 25-36).

g. With respect to claim 102, JACKSON does not disclose intermittent or continuous UV irradiation. However, CHAO teaches UV radiation may be produced from lamps in continuous or high energy bursts depending upon which is suitable for cleaving specific contaminant bonds (Column 5, lines 54-56).

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h. With respect to claims 105 and 106, JACKSON does not disclose translating the substrate during contact with the fluid. However, CHAO teaches translating the fluid in respect to a stationary substrate because the movement is necessary for cleaning specifically transport and distribution of chemical oxidants needed for sterilization and disinfection to contact all portions of the substrate (Column 8, lines 39-57). At the time of the invention it would have been obvious to one of ordinary skill in the art to translate the substrate instead of the fluid, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Response to Arguments

10. Applicant's arguments with respect to claims 26-29, 31, 34-35, 39, 41-42, 45, 52-55, 58-60, and 63-65 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 7:30am-5pm, Alternate Fridays: 7:30am-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1797

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Primary Examiner, Art Unit 1797